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DATE:

Patent Docket No. 46342/56000

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT: Toyoda et al.

Art Unit: 1636

U.S.S.N: 09/869,098

Examiner: G. Leffers

FILED: June 21, 2001

FOR: UCP-2 PROMOTER AND USE THEREOF

**CERTIFICATE OF MAILING**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450 on May 12, 2004.

By:

  
Sharon Bizokas

Mail Stop: Amendment  
Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Transmitted herewith for filing in the above-referenced patent application are the following documents:

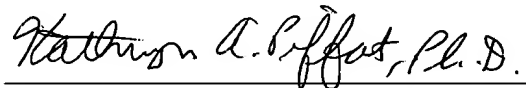
1. Amendment (24 pages)
2. Copy of the stamped postcard, the IDS, the PTO Form 1449, the references cited thereon, the European Search Report, and the Transmittal Letter (with Certificate of First Class Mailing dated October 2, 2002);
3. Information Disclosure Statement (4 pages) and 1449 Form (1 page);
4. Reference for IDS (1 reference);
5. Transmittal of Formal Drawings (1 page);
6. Formal Drawings (10 sheets);
7. Copy of the return postcard and note that the card was duly stamped by the U.S. Patent & Trademark Office (1 page);
8. Copy of the Notice of Acceptance of Application (12 pages);
9. Copy of the Transmittal Letters (with Certificate of Express Mailing) filed June 21, 2001, along with a photocopy of the diskette mailer in which the diskette was mailed (4 pages);

10. Submission of Sequence Listing (5 pages);
11. Paper Copy of Sequence Listing (2 pages);
12. Diskette Containing Sequence Listing;
13. One-Month Extension of Time (1 page);
14. Checks in the amounts of \$180.00 (IDS fee) and \$110.00 (extension fee);
15. This transmittal letter (2 pages) (x2); and
16. Return Receipt Postcard

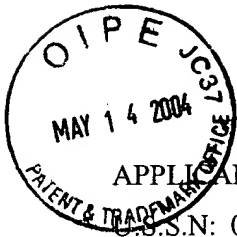
The Commissioner is hereby authorized to charge any excess fees that may be required, or credit any overpayment to Deposit Account No. 04-1105. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Date: May 12, 2004



Kathryn A. Piffat, Ph.D., (Reg. No. 34,901)  
Intellectual Property Practice Group  
EDWARDS & ANGELL, LLP  
P.O. Box 55874  
Boston, Massachusetts 02205  
Telephone: 617-439-4444



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT: Toyoda et al.

Art Unit: 1636

U.S.S.N.: 09/869,098

Examiner: G. Leffers

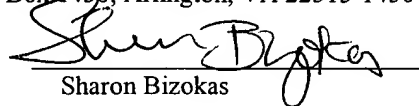
FILED: June 21, 2001

FOR: UCP-2 PROMOTER AND USE THEREOF

**CERTIFICATE OF MAILING**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450 on May 12, 2004.

By:

  
Sharon Bizokas

Mail Stop: Amendment  
Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL OF FORMAL DRAWINGS**

Attached please find:

- (a) the formal drawing(s) for this application, which have been renumbered as follows:

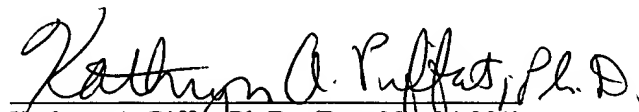
Number of Sheets      10 (Figures 1 - 5)

<u>Formerly</u>	<u>Currently</u>
1	1A
2	1B
3	1C
4	1D
5	1E
6	1F
7	2
8	3
9	4
10	5

The sequence identifier has been added to Figure 5 (Formerly Figure 10).

Respectfully submitted,

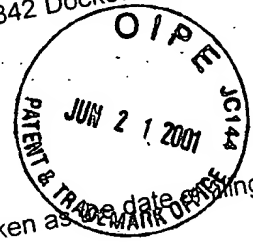
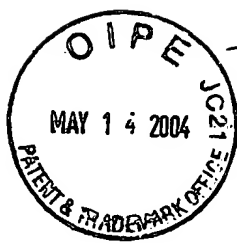
Date: May 12, 2004

  
Kathryn A. Piffat, Ph.D., (Reg. No. 34,901)  
Intellectual Property Practice Group  
EDWARDS & ANGELL, LLP  
P.O. Box 55874  
Boston, Massachusetts 02205  
Telephone: 617-439-4444

Customer No. 21874

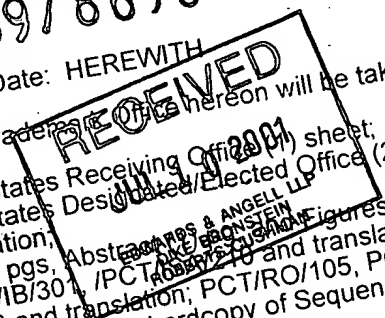
DGC/KAP

RECEIVED IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Mailing Date: June 21, 2001 Attorney/ DGC/KAP/jah Client: 46342 Docket No.: 56000  
Inventor(s): Yukio TOYODA, Makoto KOBAYASHI, Shigeru IGAKI  
Title: UCP-2 Promoter DNA 09/869098  
Serial No.: N/A Filing Date: HEREWITH

Dating stamp of the Patent and Trademark Office hereon will be taken as prima facie evidence of:  
Transmittal Letter to the United States Receiving Office (1) sheet;  
Copy of the International Application Designated/Elected Office (2) pages;  
Translation of Specification (29) pgs, Abstract (1) page, Figures 1-10 (10) Sheets;  
Form(s) PCT/RO/101, /IB/304, /IB/305, /PCT/RO/105, PCT/IB/308;  
/PCT/IB/332, and /PCT/IPA/416 and translation; PCT/RO/105, PCT/IPEA/408;  
Computer Readable Sequence Disk; and a hardcopy of Sequence Listing (2) pages;  
Statement Regarding Sequence Listing (1) page;  
Information Disclosure Statement (5) pgs, and prior art documents;  
Check for \$1,118.00 - filing fee for National Phase PCT Application in U.S.;  
Authorization to charge Deposit Account;  
Certificate of Express Mail (1) page and  
Mail Date Postcard.  
DUE DATE: JUNE 24, 2001



JC17 Rec'd PCT/PTO 21 JUN 2001

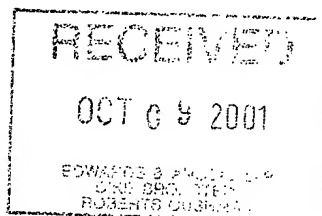
DEC/KM  
56000  
(46342)



<input type="checkbox"/> Commissioner for Patents, Box PCT, United States Patent and Trademark Office, Washington, D.C. 20231, www.uspto.gov		
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U.S. APPLICATION NUMBER NO. 09/869,098	FIRST NAMED APPLICANT Yukio Toyoda	ATTY. DOCKET NO. 46342/56000
---	---------------------------------------	---------------------------------

David G Conlin  
Dike Bronstein Roberts & Cushman  
130 Water Street  
Boston, MA 02109



INTERNATIONAL APPLICATION NO. PCT/JP99/07198	
I.A. FILING DATE 12/22/1999	PRIORITY DATE 12/24/1998

**CONFIRMATION NO. 9857**  
**371 ACCEPTANCE LETTER**



\*OC000000005816101\*

Date Mailed: 10/02/2001

## NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.494 OR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as an Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

<u>09/20/2001</u>	<u>06/21/2001</u>
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF RECEIPT OF ALL 35 U.S.C. REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- U.S. Basic National Fee
- Biochemical Sequence Diskette
- Biochemical Sequence Listing
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- Information Disclosure Statements
- Oath or Declaration

- Preliminary Amendments

---

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

---

SHAKEEL AHMED

Telephone: (703) 305-3659

PART 1 - ATTORNEY/APPLICANT COPY

TRANSMITTAL LETTER TO THE  
UNITED STATES RECEIVING OFFICE

Date	June 21, 2001
International Application No.	PCT/JP99/07198
Attorney Docket No.	46342/56000

I. Certification under 37 CFR 1.10 (if applicable)

EL895417578US
Express Mail mailing number

June 21, 2001
Date of Deposit

I hereby certify that the application/correspondence attached hereto is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Assistant Commissioner for Patents, Washington, D.C. 20231.

<i>Judith A. Herrick</i>
Signature of person mailing correspondence

JUDITH A. HERRICK
Typed or printed name of person mailing correspondence

II. ☒ New International Application

TITLE	UCP-2 PROMOTER DNA
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Earliest priority date (Day/Month/Year)
24 DECEMBER 1998

**SCREENING DISCLOSURE INFORMATION:** In order to assist in screening the accompanying international application for purposes of determining whether a license for foreign transmittal should and could be granted and for other purposes, the following information is supplied. (Note: check as many boxes as apply):

- A. ☒ The invention disclosed was **not** made in the United States.
- B. ☒ There is no prior U.S. application relating to this invention.
- C. ☐ The following prior U.S. application(s) contain subject matter which is related to the invention disclosed in the attached international application. (NOTE: priority to these applications may or may not be claimed on form PCT/RO/101 (Request) and this listing does not constitute a claim for priority).

application no.		filed on	
application no.		filed on	

- D. ☐ The present international application ☐ is identical ☐ contains less subject matter than that found in the prior U.S. application(s) identified in paragraph C.
- E. ☐ The present international application ☐ contains additional subject matter not found in the prior U.S. application(s) identified in paragraph C. above. The additional subject matter is found on pages  and ☐ DOES NOT ALTER ☐ MIGHT BE CONSIDERED TO ALTER the general nature of the invention in a manner which would require the U.S. application to have been made available for inspection by the appropriate defense agencies under 35 U.S.C. 181 and 37 CFR 5.1. See 37 CFR 5.15

III. ☐ A Response to an Invitation from the RO/US. The following document(s) is (are) enclosed:

- A. ☐ A Request for An Extension of Time to File a Response
- B. ☐ A Power of Attorney (General or Regular)
- C. ☐ Replacement pages:

pages		of the request (PCT/RO/101)	pages		of the figures
pages		of the description	pages		of the abstract
pages		of the claims			

- D. ☐ Submission of Priority Documents

Priority document		Priority document	
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- E. ☒ Fees as specified on attached Fee Calculation sheet form PCT/RO/101 annex

IV. ☐ A Request for Rectification under PCT 91 ☐ A Petition ☐ A Sequence Listing Diskette

V. ☒ Other (please specify):

The person  
signing this  
form is the:

<input type="checkbox"/> Applicant	KATHRYN A. PIFFAT, Ph.D.
<input checked="" type="checkbox"/> Attorney/Agent (Reg. No.) 34,901	Typed name of signer
<input type="checkbox"/> Common Representative	<i>Kathryn A. Piffat, Ph.D.</i> Signature

## TRANSMITTAL LETTER TO THE UNITED STATES

DESIGNATED/ELECTED OFFICE (DO/EO/US)

CONCERNING A FILING UNDER 35 U.S.C. 371

46342/56000

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

INTERNATIONAL APPLICATION NO.

PCT/JP/07198

INTERNATIONAL FILING DATE

22 December 1999

PRIORITY DATE CLAIMED

24 December 1998

TITLE OF INVENTION

UCP-2 Promoter DNA

APPLICANT(S) FOR DO/EO/US

Yukio TOYODA, Makoto KOBAYASHI, Shigeru IGAKI

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☒ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☒ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

## Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

Sequence Listing on Computer disk and hardcopy (2) pages;

Information Disclosure Statement (5) pages;

Form/IB/304 Form PCT/RO/101

Form/IB/301 Form/PCT/IPEA/416

PCT/IB/332

PCT/IB/332

PCT/RO/105

PCT/IPEA/408



U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR	INTERNATIONAL APPLICATION NO. <b>PCT/JP/07198</b>	ATTORNEY'S DOCKET NUMBER <b>46342/56000</b>
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24. The following fees are submitted:

**BASIC NATIONAL FEE ( 37 CFR 1.492 (a) (1) - (5) ) :**

☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... **\$1000.00**

☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... **\$860.00**

☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... **\$710.00**

☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... **\$690.00**

☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... **\$100.00**

**ENTER APPROPRIATE BASIC FEE AMOUNT =**

Surcharge of **\$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	21 - 20 =	1	x \$18.00	<b>\$18.00</b>
Independent claims	6 - 3 =	3	x \$80.00	<b>\$240.00</b>
Multiple Dependent Claims (check if applicable). <input type="checkbox"/>				<b>\$0.00</b>
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$1,118.00</b>
<input type="checkbox"/> Applicant claims small entity status. (See 37 CFR 1.27). The fees indicated above are reduced by 1/2.				<b>\$0.00</b>
<b>SUBTOTAL =</b>				<b>\$1,118.00</b>
Processing fee of <b>\$130.00</b> for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				<b>\$0.00</b>
<b>TOTAL NATIONAL FEE =</b>				<b>\$1,118.00</b>
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input type="checkbox"/>				<b>\$0.00</b>
<b>TOTAL FEES ENCLOSED =</b>				<b>\$1,118.00</b>
				Amount to be refunded \$
				charged \$

**CALCULATIONS PTO USE ONLY**

a. ☒ A check in the amount of **\$1,118.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \_\_\_\_\_ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **04-1105** A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

**SEND ALL CORRESPONDENCE TO:**

David G. Conlin, Esq. (Reg. No. 27,026)

Kathryn A. Piffat, Ph.D., Esq. (Reg. No. 34,901)

Dike, Bronstein, Roberts & Cushman

Intellectual Property Practice Group

EDWARDS & ANGELL, LLP

P.O. Box 9169

Boston, MA 02209

Telephone: 617/439-4444

*Kathryn A. Piffat, Ph.D.*

SIGNATURE

**Kathryn A. Piffat, Ph.D.**

NAME

**34,901**

REGISTRATION NUMBER

**June 21, 2001**

DATE

From

Edwards, R. Angel

PO Box 9169

Baltimore, MD 21208

To

Re: PC 07143-101

PC 07143-101

Paydette

USPS, Premier Mail

Our ref: 176342/56006



Self-sealing Mailer for 3 1/2" Disks

Handle with care

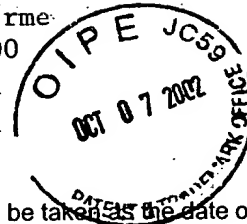
Do not bend or fold. Avoid magnetic fields



Doc/KAP  
146342/56000

Mailing Date: October 2, 2002  
Client: 46342  
Inventors: Y. Toyoda et al.  
Serial No.: 09/869,098  
Filing Date: June 21, 2001

Attorney/Sec: KAP/rme  
Docket No.: 56000  
Patent No.:  
Grant Date:



The dating stamp of the Patent and Trademark Office hereon will be taken as the date of filing of:

1. Information Disclosure Statement (4 pages);
  2. Form PTO-1449;
  3. Reference CA - Cortez-Pinto, Biochem Biophys Res Commun;
  4. Reference CB - Yamada M. et al, FEBS Letters;
  5. Reference CC - Bouillaud F., Database EMBL Online!;
  6. Reference CD - Kelly LJ., Endocrinology;
  7. Reference CE - Yubero P, Biochemical and Biophysical Research Communications;
  8. Reference CF - Jazek P., International Journal of Biochemistry and Cell Biology;
  9. This return postcard.
  10. Copy of European Search Report.
  11. Transmittal Letter (x2).
- Due Date:



Attorney Docket No. 46342/56000

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT: Y. TOYODA et al. EXAMINER: Not Yet Known  
SERIAL NO.: 09/869,098 **COPY** GROUP: Not Yet Known  
FILED: June 21, 2001  
FOR: UCP-2 Promoter DNA and Use Thereof (formerly UCP-2 Promoter DNA)

\*\*\*\*\*  
**CERTIFICATE OF FIRST CLASS MAILING**

I hereby certify that this correspondence and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, Washington, DC, 20231 on **October 2, 2002**.

*Regina M. Edwards*  
Regina M. Edwards

\*\*\*\*\*  
Commissioner for Patents  
Washington, D.C. 20231

**COPY**

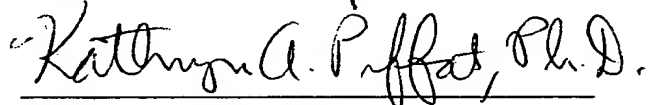
**TRANSMITTAL LETTER**

Transmitted herewith for filing in the above-referenced patent application are the following documents:

- 1) Information Disclosure Statement (4 pages);
- 2) Form PTO-1449;
- 3) Reference CA – Cortez-Pinto, Biochem Biophys Res Commun;
- 4) Reference CB – Yamada M. et al., FEBS Letters;
- 5) Reference CC – Bouillaud F., Database EMBL Online!;
- 6) Reference CD – Kelly LJ., Endocrinology;
- 7) Reference CE – Yubero P, Biochemical and Biophysical Research Communications;
- 8) Reference CF – Jazek P., International Journal of Biochemistry and Cell Biology.
- 9) This transmittal letter (x2); and
- 10) Return Postcard.

The Commissioner is hereby authorized to charge any excess fees that may be required, or credit any overpayment to Deposit Account No. 04-1105. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

A handwritten signature in cursive script that reads "Kathryn A. Piffat, Ph.D." The signature is written in dark ink and is positioned above a horizontal line.

Kathryn A. Piffat, Ph.D.

Reg. No.: 34,901

DBRC, Intellectual Property Practice  
Group of

EDWARDS & ANGELL, LLP

P.O. Box 9169

Boston, Massachusetts 02209

Tel.: 617-439-4444

Fax: 617-439-4170

Date: October 2, 2002

BOS2\_314764.1